JC07 Rec'd PCT/PTO 28 JAN 2002

FORM PTO-1390 (REV. 12-2001) U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY 'S DOCKET NUMBER: B 0410/7284

U.S. APPLICATION NO. (If known, see 37 CFR 1.5): 10/048205

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/US00/20574	28 July 2000	July 30, 1999

TITLE OF INVENTION: Improved Implant Anchor Systems

APPLICANT(S) FOR DO/EO/US: Richard A. Gambale

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [ ] This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. [X] The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [ ] is attached hereto (required only if not communicated by the International Bureau).
   b. [ ] has been communicated by the International Bureau.
   c. [X] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [ ] An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. [ ] is attached hereto.
   b. [ ] has been previously submitted under 35 U.S.C. 154(d)(4).
7. [X] Amendments to the claims of the International Aplication under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are attached hereto (required only if not communicated by the International Bureau).
   b. [ ] have been communicated by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [X] have not been made and will not be made.
8. [ ] An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. [ ] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [ ] An English lanugage translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [ ] A FIRST preliminary amendment.
14. [ ] A SECOND or SUBSEQUENT preliminary amendment.
15. [ ] A substitute specification.
16. [ ] A change of power of attorney and/or address letter.
17. [ ] A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. [ ] A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. [ ] A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. [ ] Other items or information:

10048205 020802

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
10/048205	PCT/US00/20574	B0410/7284

21. [X] The following fees are submitted:

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):	CALCULATIONS PTO USE ONLY
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO **$1040.00**	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$890.00**	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **$740.00**	
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$710.00**	
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) **$100.00**	
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 740.00
Surcharge of **$130.00** for furnishing the oath or declaration later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	23 - 20 =	3	x **$18.00**	$ 54.00
Independent claims	3 - 3 =	0	x **$84.00**	$ -0-
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ **$280.00**	$
TOTAL OF ABOVE CALCULATIONS =				$ 794.00
[ ] Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.			+	$
SUBTOTAL =				$
Processing fee of **$130.00** for furnishing the English translation later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				$
TOTAL NATIONAL FEE =				$ 794.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$
TOTAL FEES ENCLOSED =				$ 794.00
			Amount to be refunded:	$
			charged:	$

a. [X] A check in the amount of $ 794.00 to cover the above fees is enclosed.

b. [ ] Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-1721. A duplicate copy of this sheet is enclosed.

d. [ ] Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

John F. Perullo
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75 State Street
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John F. Perullo
SIGNATURE

JOHN F. PERULLO
NAME

39,498
REGISTRATION NUMBER

IMPROVED IMPLANT ANCHOR SYSTEMS

Field of the Invention

This invention relates to tissue implant devices and methods of their use. In particular, the devices and methods concern systems for anchoring the implants in tissue so that they do not migrate after implantation.

Background of the Invention

There are a variety of applications for tissue implant devices in the human body. Such applications include electrical pacing leads or other tissue monitoring devices or tissue support structures such as endoluminal stents. A device implanted in tissue may experience migratory forces applied by movement of the surrounding tissue into which the device has been implanted. Migration is especially a problem in muscle tissue that regularly contracts and relaxes around the device. Because the device is static and is relatively inflexible, rather than absorbing the forces applied by the tissue, those forces act on the device to move it in the tissue. Migration of the device ultimately may lead to ejection of the device from the tissue. An ejected device could prove harmful to a patient if it enters the blood stream and blocks blood flow to a critical organ such as the brain.

Perhaps the most regular aggressive migratory forces created by muscle tissue may be experienced by implant devices which are placed in heart tissue. Because the heart muscle regularly contracts and relaxes in an exaggerated fashion to pump blood through the ventricle, implant devices located within that tissue have significant forces applied upon them. For example, the myocardial tissue comprising the exterior wall of the heart at the left ventricle may increase in thickness by forty to sixty percent with each contraction. Conventional methods of anchoring a device to tissue such as by stapling or suturing prove difficult in applications where there is exaggerated and constant movement of the subject tissue because it is difficult to accurately apply a suture or staple to the intended location.

Implant devices for the heart have been disclosed in U.S. patent 5,429,144 (Wilk) and in U.S. patent 5,810,836 (Hussein et al.) for the purpose of restoring blood flow to the tissue of the heart. Conventional treatments of restoring blood flow to

heart tissue such as coronary artery bypass grafting have been supplanted in recent years by various methods of transmyocardial revascularization (TMR). TMR methods include creating channels into tissue of the heart either by needle acupuncture or coring with a hypodermic tube or by laser or mechanical ablative methods. Hussein and Wilk attempt to maintain the patency of such channels by a placement of a mechanical implant device to the heart tissue to support an open pathway through which blood may flow. The Hussein patent discloses several stent embodiments that are delivered through the epicardium of the heart into the myocardium and positioned to be open to the left ventricle.

Due to the exaggerated migration forces experienced by an implant device in heart tissue as described above, it would be desirable to provide devices and methods for securely anchoring an implant in an associated dynamic region of tissue. It is a general object of the present invention to provide such an anchoring system for tissue implants, especially those intended for placement in the heart that may be useful for revascularization of the heart tissue by various mechanisms.

Summary of the Invention

The present invention provides implant devices configured to become anchored within tissue so that they do not migrate despite experiencing aggressive migration forces applied by the highly dynamic movement of muscle tissue that surrounds them. Additionally, methods for placing the devices so that they remain securely anchored within the tissue are provided. The devices are comprised of a flexible body, preferably formed from a helical wound spring. In a preferred embodiment the spring is wound from a ribbon-like filament having series of barbs or ridges formed along the proximal facing edge of the wound ribbon.

The devices of the present invention may be delivered to the intended tissue location percutaneously, through a catheter based system, transthoracically or surgically. Although the inventive devices and methods can be applied to implants intended for use in any region of the body, it is believed that the anchor systems are especially useful as applied to implant devices for the heart configured to treat ischemia. Flexible implant devices may be configured to promote angiogenesis

through a variety of mechanisms examples of which are described in detail in pending U.S. patent application serial nos. 09/164,173, 09/211,332 and 09/299,795.

Generally, the spring implant devices may be considered to have a body having proximal and distal portions. In the present application, proximal is understood to mean the direction leading external to the patient and distal is understood to mean any direction leading internally to the patient. The implant devices discussed herein are delivered into the tissue in a distal direction so that the body is implanted within the tissue and the proximal end of the device is approximately flush with the tissue surface or slightly submerged under the surface. The configuration of the barbs to resist migration of the device proximally back out of the tissue. Additionally, the barbs may serve to resist rotational movement of the device so that it does not "unscrew" out of the tissue.

In an embodiment of the invention, a flexible implant device formed from a helical spring body may be formed from a filament having a non-circular cross-section. For example, a filament having a rectangular cross-section may serve to prevent migration through the tissue in the axial direction by several mechanisms. When the helical coil is wound such that the major axis of the rectangular cross-section is substantially perpendicular to the longitudinal axis of the body of the device greater axial flexibility is imparted to the spring, while maintaining sufficient radial stiffness to resist crushing by the tissue, than would be possible with a round cross-sectional filament material. Increased axial flexibility of the device permits it to move with surrounding tissue, absorbing forces that would otherwise tend to push the device out of position in the tissue. Additionally, as surrounding tissue herniates through the individual coils of the device, the orientation of the major axis of the rectangular cross-section of the filament to be perpendicular to the longitudinal axis of the device presents a larger surface area engaging the tissue to resist axial migration.

Alternatively, the major axis of the rectangular cross-section filament may be oriented at an angle that is acute to the longitudinal axis of the device, so that the filament is canted in the proximal direction, to facilitate insertion of the device in the distal direction during implantation into the tissue. The canted orientation of the rectangular cross-sectional filament still provides the flexibility benefits of the

perpendicular orientation discussed above and may enhance anchoring capability by presenting a leading proximal facing edge that serves to grip into tissue.

Barbs formed on the proximally facing edge of the finished may be formed on the ribbon prior to winding into its coiled shape. Preferably, the ribbon is formed having barbed shapes along at least one edge of the ribbon by an etching process. A number of ribbons may be etched on a sheet of suitable material, such as stainless steel, at once. After the ribbons are formed on the sheet of material, they may be individually detached from the sheet and wound on a spring winding machine to form a coil by conventional spring winding techniques.

A variety of filament materials may be used such as surgical grade stainless steels. Other materials may be used to vary the modulus of elasticity of the filament. Additionally, flexibility of the coil implant may be varied along the length of the coil, not only by varying spacing between coils and diameter of the filament along its length, but also by using two or more different filament materials along the length of the filament that have different moduli of elasticity.

It is an object of the present invention to provide a tissue implant device that resists migration from the tissue into which it is implanted by offering improved anchoring capability.

It is another object of the present invention to provide a tissue implant device having an anchor mechanism that is easy to integrate into small mechanical devices.

It is yet another object of the present invention to provide an implant device that resists migration by its inherent flexibility and ability to absorb migratory forces exerted by surrounding tissue.

It is another object of the invention to provide an implant device that utilizes an anchoring mechanism that is submerged beneath the surface of the tissue into which the device is implanted.

It is yet another object of the invention to provide a method of implanting a tissue implant device so that it remains anchored in the tissue.

Brief Description of the Drawings

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following further description thereof, with reference to the accompanying diagrammatic drawings wherein:

FIG. 1 is a side view of an alternate embodiment of the tissue implant device;

FIG. 2 is a partial sectional view of the tissue implant device shown in FIG. 13;

FIG. 3 is a partial sectional view of a variation of the tissue implant device shown in FIG. 2;

FIG. 4 is a side view of a preferred embodiment of the tissue implant device having barbs;

FIG. 5 is a side view of an alternate embodiment of the tissue implant device having barbs;

FIG. 6 is a top view of a sheet of material having a plurality of etched ribbon forms through out its surface.

FIG. 7 is a magnified view of one of the etched ribbon forms on the sheet shown in FIG. 6:

FIG. 8A. is a side view of a tissue implant device delivery system;

FIG. 8B is a detailed side view of the distal end of the tissue implant device delivery system; and

FIG. 8C is a detailed side view of the distal end of the tissue implant device delivery system carrying an implant.

Description of the Illustrative Embodiments

The implant devices of the present invention are particularly useful in treating ischemic tissue such as that often occurs in a myocardium of the heart. The implant device may be inserted into the myocardium through the epicardial surface at an entry site such that the device extends the majority of the thickness of the myocardium towards endocardial surface.

FIG. 1 shows an embodiment of a tubular implant device. The canted coil device 40 is formed from a filament 42 of rectangular cross-section such as a strand of flat wire. As shown in FIG. 2, the coil is formed so that the major cross-sectional

axis 47 of the rectangular wire is oriented at an acute angle to the longitudinal axis 50 of the coil 40. The orientation gives each turn 46 of the coil a projecting edge 44, which tends to claw into tissue to serve as an anchoring mechanism for the device.

FIG. 3 shows a segment of a wrapped ribbon implant embodiment. The implant 60 is formed by a filament of a rectangular cross-sectional filament around a ribbed mandrel. In the present embodiment, the major axis 47 of the rectangular cross-section ribbon is oriented substantially perpendicular to the longitudinal axis 50 of the implant, as is shown in FIG. 3. In this configuration, the major axis 47 of the coils 42 of the rectangular ribbon do not extend radially from the longitudinal axis 50 of the implant 40 at an acute angle. With greater coil surface area extending away from the longitudinal axis of the implant, the implant is believed to be more stable and less likely to migrate once implanted within the myocardium. The implant is preferably formed from 316 stainless steel rectangular cross-section forming wire. Preferred dimensions for the rectangular cross-section filament are on the order of .003 inches to .005 inches for the minor axis width and .015 to .018 inches for the major axis.

FIG. 4 shows a preferred embodiment of the wrapped ribbon device 62 having a plurality of barbs 64 formed on the proximally facing edge 66 of the ribbon. The device may only have one barb, but a plurality of barbs is preferred. Each barb has a tapering penetrating shape configured to claw into tissue to resist migration of the device. The barbs may be a variety of shapes such as the curved shape shown in the figures or a sharp pointed shape (not shown). Barbs 64 formed on the spring embodiment shown in Figure 1 tend to project radially outward from the longitudinal axis of the device at an acute angle, as shown in Figure 4. The radial projection of the barbs may help to anchor the implant within tissue.

Alternatively, as shown in Figure 5, the spring device 68 may have coil 70 oriented such that the major their axis is parallel to the longitudinal axis of the device and barbs 64 are curved radially outward from the proximally facing edge 72 of each coil 70. The barbs may be curved by bending prior to wrapping of the ribbon into a coil form.

Ribbon material having integrally formed barbs may be formed by variety of methods; however, chemically etching of the ribbon having barbed shapes is

preferred. FIG. 6 shows a top view of a sheet 76 of material having a plurality of ribbon forms 78 that have been etched through its surface. FIG. 7 shows a magnified view of a single ribbon form 78 comprising a linear ribbon form 79 of a plurality of barb 64, which will ultimately be wrapped into the spring device. Each form 78 remains joined to the sheet 76 after etching by links 77. Ribbon forms are preferably created by a photo etching process. In this process, a photo resistant coating is first applied over the entire sheet of material. Preferably a sheet of stainless steal material is used to having a thickness equivalent to the desired thickness of the final ribbon product as has been defined above. After application of the coating a template having the desired pattern of shapes (a plurality of ribbons having barbs with spare material between each ribbon form) is placed over the sheet. Next the sheet is applied to remove the protective coating from areas of the sheet where material is to be removed. The resultant sheet etchant protective coating only over areas where material is to remain. The sheet is then exposed to a chemical etchant which removes material from the sheet in the unprotected areas. The resultant 76 sheet shown FIG. 6 has numerous perforations where material has been removed the chemical etchant process provides a quick and economical way to form numerous pieces of ribbon stock having accurately formed barbs. The ribbon forms an easily finished sheet by breaking or cutting links 77. The ribbon may be wrapped in to the helical spring implant device as is described above.

The implant devices of the present invention may be delivered to their intended tissue location surgically. FIGS. 8A - 8C show an example of a surgical delivery device that may be used to deliver the implants into tissue such as that of the myocardium of the heart. The delivery device, shown in FIG. 8A, comprises an obturator 80 that includes a main shaft 82, by which it can be gripped and manipulated. The distal end 81 of the shaft 82 is shown in detail in FIG 8B and includes a reduced diameter device support section 84 having a sharp distal tip 86 adapted to pierce tissue. The diameter of the shaft segment 84 is such as to fit closely within the interior of the devices. The proximal end of the segment 84 terminates in a shoulder 88 formed at the junction of a proximally adjacent, slightly enlarged diameter portion 90 of the shaft. The distal end of the device support

segment 84 may include a radially projecting pin 92 dimensioned to project and fit between adjacent turns of the coils of a device. The pin 92 engages the coils in a thread-like fashion so that after the assembly has been inserted into the tissue, the obturator 80 can be removed simply by unscrewing the obturator to free it from the implanted coil. Alternatively, the obturator may be configured without the projecting pin 92 so that the device can be slipped on and off the obturator, without screwing. When an implant device 2 is mounted on the obturator 80, as is shown in FIG. 8C the proximal end of the device may bear against the shoulder 88, and the tail 28, if so equipped may extend along the segment 90 of the obturator.

In use, the intended tissue location is first accessed surgically, such as by a cut-down method. The obturator, with an implant device loaded on to segment 84, then may be advanced into the tissue to deliver the implant. The sharp tip pierces the tissue permitting the obturator and implant to be pushed inward into the tissue. In the example of delivery to the myocardium, the epicardial surface of the heart is accessed and penetrated by the obturator to deliver the implant. The shoulder 88 prevents proximal movement of the implant along segment 84 during delivery. Preferably, the distal end of the obturator is projected to, and slightly beyond, the endocardium to place the implant device. The obturator then may be unscrewed and separated from the implant device. If the obturator is configured without the pin 92, the obturator may be withdrawn directly from the device and the tissue. Simply applying light closure pressure to the epicardial puncture will cause the puncture hole to clot at the epicardium.

Generally, surgical grade stainless steels are used to fabricate the implant devices discussed above, but other materials having different moduli of elasticity such as nickel titanium alloys can be used.

From the foregoing it will be appreciated that the invention provides a novel approach to providing an anchoring system for implant devices. The devices and methods of the present invention are simple and easy to apply to a wide range of implant designs.

It should be understood however, that the foregoing description of the invention is intended merely to be illustrative thereof and that other modifications, embodiments

and equivalents may be apparent to those who are skilled in the art without departing from its spirit. Having thus described the invention what we desire to claim and secure by letters patent is:

Claims

1. A tissue implant device configured to resist migration in tissue comprising a flexible helical spring having at least one barb that engages surrounding tissue.

2. An implant as defined in claim 1 wherein the at least one barb is proximally facing.

3. The implant as defined in claim 1 wherein the barb faces radially outward from the spring.

4. An implant as defined in claim 1 wherein the barb has a rounded contour.

5. An implant as defined in claim 1 wherein the at least one barb has a sharpened point configured for engaging tissue.

6. An implant as defined in claim 1 wherein the helical spring is formed from a filament having a rectangular cross-sectional profile.

7. An implant device as defined in claim 6 wherein the helical spring comprises a plurality of coils, each having a proximally facing edge along which is formed a plurality of barbs.

8. An implant as defined in claim 1 wherein the spring is formed from a plurality of materials each having different moduli of elasticity.

9. An implant as defined in claim 1 wherein the spring is formed from metal.

10. An implant as defined in claim 9 wherein the metallic material is stainless steel.

11. An implant as defined in claim 1 wherein the moduli of elasticity of the spring varies along its length.

12. An implant as defined in claim 1 wherein the spring is formed from a filament that has been etched from a flat sheet of material and wound into a spring configuration.

13. An implant as defined in claim 12 wherein at least one barb is formed into the filament during the etching process.

14. A method of forming a tissue implant device comprising:

forming a ribbon shaped form in a sheet of material by a photochemical etching process;

separating the ribbon formed from the sheet of material; and

wrapping the ribbon form into a helical coil shape, plastically deforming the ribbon so that it retains the coil shape.

15. The method as defined in claim 14 further comprising:

forming at least one barb shape on an edge of the ribbon forms so that the resultant coiled ribbon has at least one projecting barb along the edge.

16. A method as defined in claim 15 wherein at least one barb is formed along an edge that will be proximally facing after the ribbon is wrapped into a coil shape.

17. A method as defined in claim 15 wherein a plurality of barb shapes are formed along an edge of the ribbon form so that the resultant coil ribbon has a plurality of projecting barbs along one edge of the coil.

18. A method of forming a tissue implant device as defined in claim 15 further comprising forming a plurality of ribbons in a single sheet of material by photochemical etching process.

5

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
8 February 2001 (08.02.2001)

PCT

(10) International Publication Number
WO 01/08602 A1

(51) International Patent Classification[7]: A61F 2/06, A61M 25/00

(21) International Application Number: PCT/US00/20574

(22) International Filing Date: 28 July 2000 (28.07.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/146.470 30 July 1999 (30.07.1999) US

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(81) Designated States *(national)*: CA, JP, MX, US.

(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published:
— *With international search report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 01/08602 A1

(54) Title: IMPROVED IMPLANT ANCHOR SYSTEMS

(57) Abstract: The present invention provides implant devices configured to become anchored within tissue so that they do not migrate despite experiencing aggressive migration forces applied by the highly dynamic movement of muscle tissue that surrounds them. Additionally, methods for placing the devices so that they remain securely anchored within the tissue are provided. The devices are comprised of a flexible body, preferably formed from a helical wound spring. In a preferred embodiment the spring is wound from a ribbon-like filament having series of barbs or ridges formed along the proximal facing edge of the wound ribbon. The ribbon-like filament may be etched from a flat sheet of material, having barbs formed along one edge. The filament may then be wrapped into a helical coil shape to take the form of an implant having barbs formed along the proximally facing edge of each coil to resist migration.

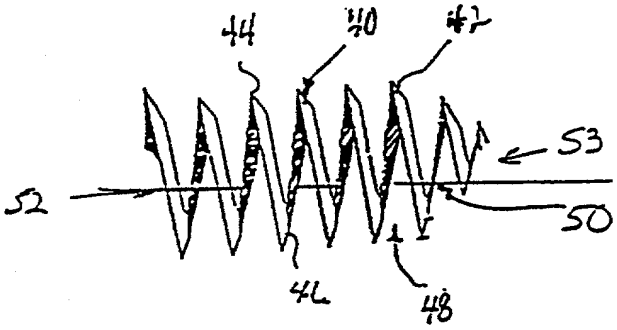


FIG. 1

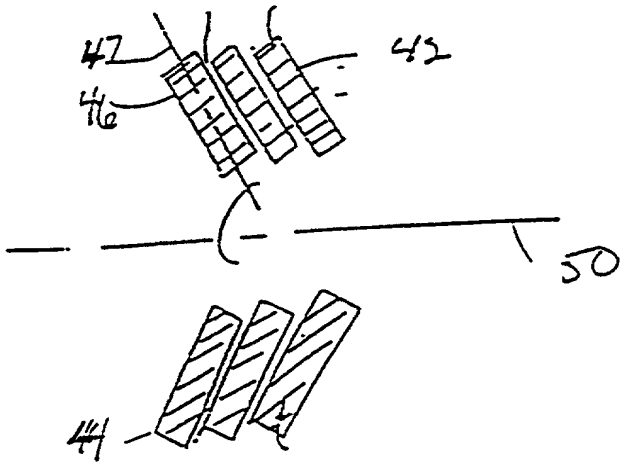


FIG. 2

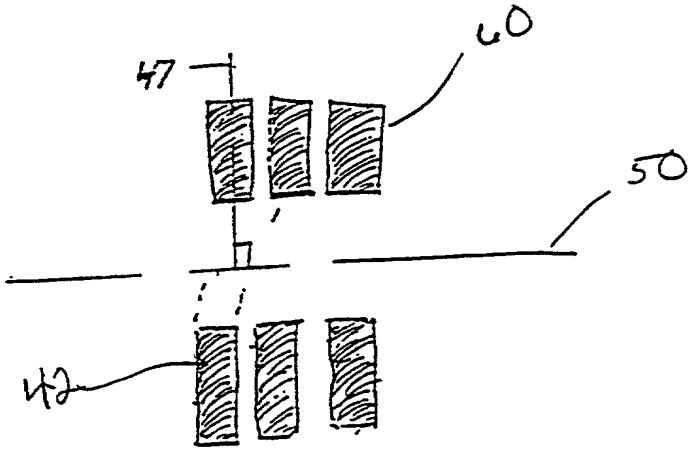


FIG. 3

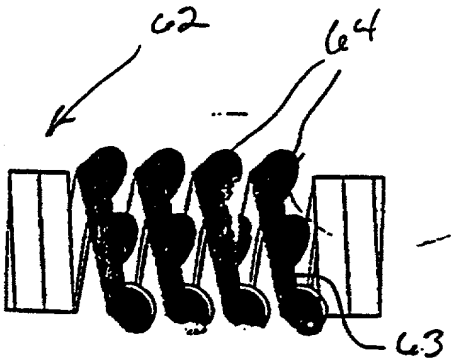


FIG. 4

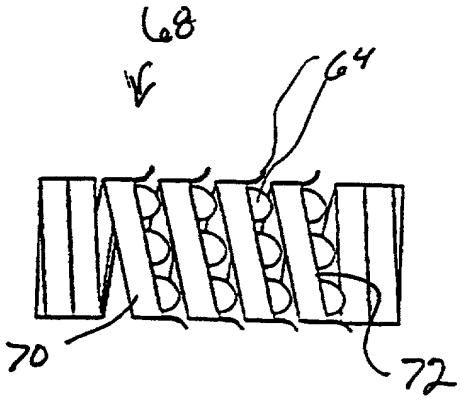


FIG. 5

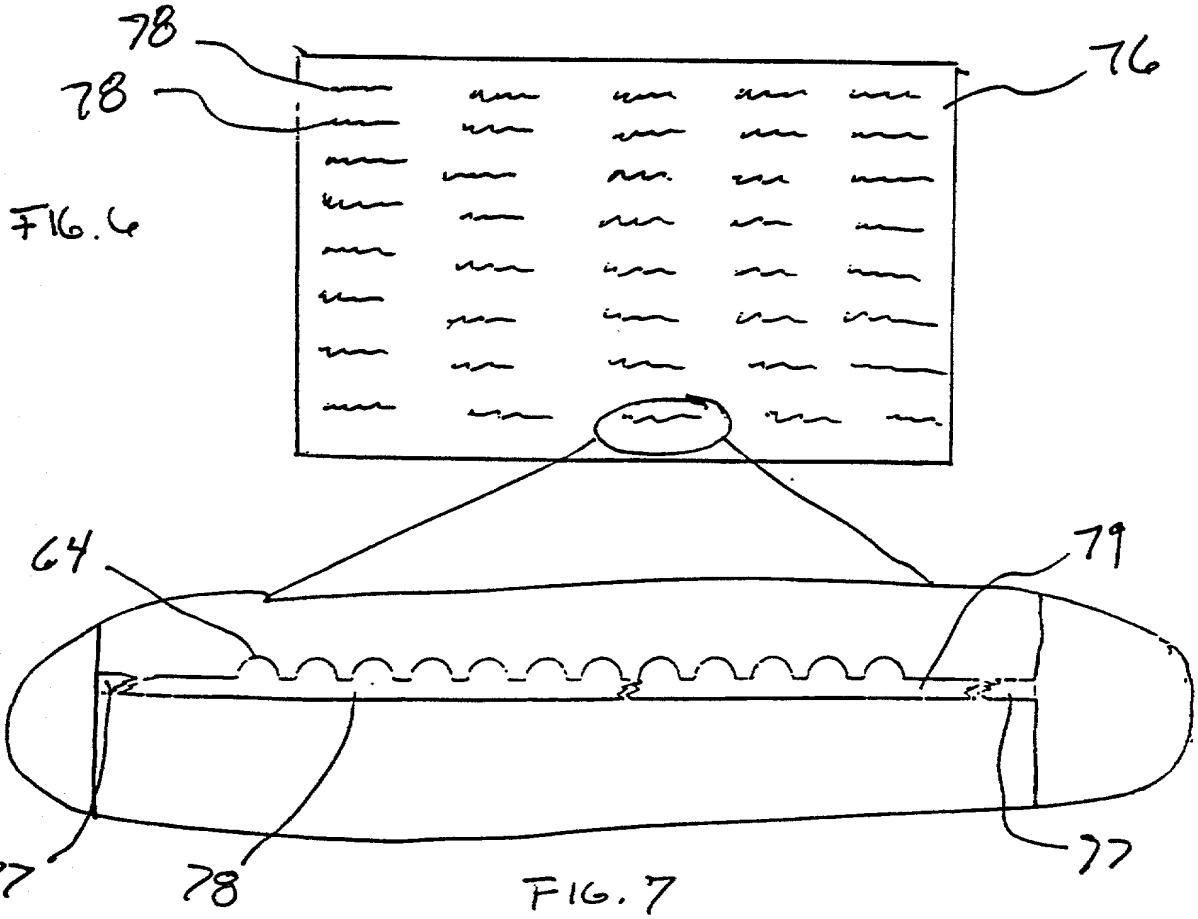


FIG. 6

FIG. 7

FIG. 8A

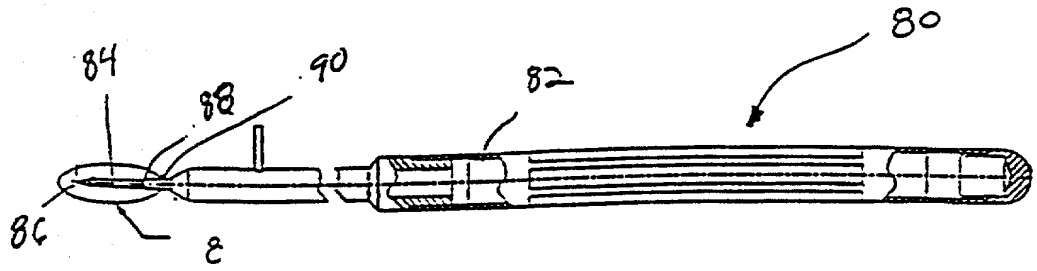


FIG. 8B

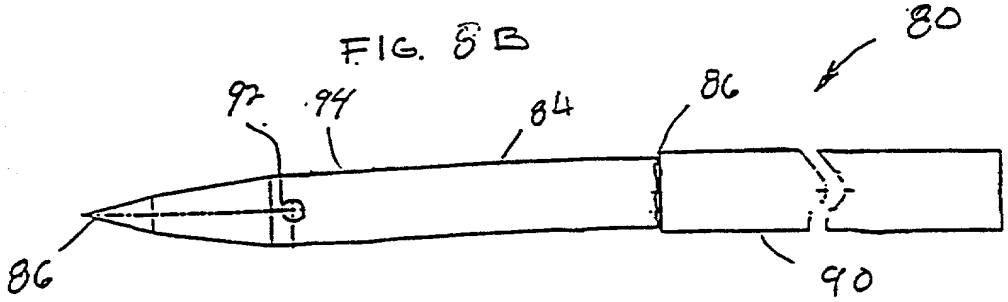
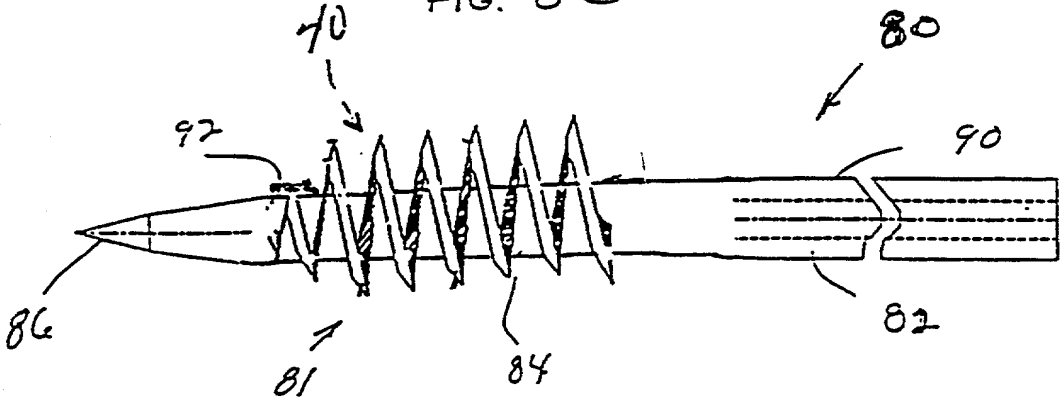


FIG. 8C



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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted with Initial Filing **OR** ☒ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	B0410/7284
First Named Inventor	Gambale, Richard A.
COMPLETE IF KNOWN	
Application Number	10/048,205
Filing Date	01/28/02
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

IMPROVED IMPLANT ANCHOR SYSTEMS

(Title of the Invention)

the specification of which
☐ is attached hereto
OR
☒ was filed on (MM/DD/YYYY) July 28, 2000 as United States Application Number or PCT International Application Number PCT/US00/20574 and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 356(b) of any foreign application(s) for patent or inventor's certificate, or 356(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	
60/146,470	07/30/1999	☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

Burden Hour Statement: This form is estimated to take 0.4 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

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DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)
PCT/US00/20574	07/28/00	

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02C attached hereto.

As a named inventor, I hereby appoint the following registered practioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

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OR

☐ Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☒ Customer Number or Bar Code Label 022832 OR ☐ Correspondence address below

Name					
Address					
Address					
City		State		ZIP	
Country		Telephone		Fax	

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Richard A.	Gambale

Inventor's Signature	Richard A Gambale					Date	04/23/02
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City	Tyngsboro	State	MA	ZIP	01879	Country	US

☐ Additional inventors are being named on the ___ supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto